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510-k Summary

Pursuant to 21 CFR 807.92 the following summary is submitted.

1. Submitter's name-
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2. Humphrey OCT (Optical Coherence Tomography) Scanner
   Optical Coherence Tomography Scanner

3. We are claiming substantial equivalence to the OCT predicate device, which already has market clearance.

4. In order to properly understand the Humphrey version of Optical Coherence Tomography Scanners you must understand how an Optical Coherence Tomography Scanner works. In general OCT Scanners permit the user to obtain and analyze cross-sectional tomograms of ocular tissue in a non-contact and non-invasive manner. The Humphrey Optical Coherence Tomography Scanner measures optical reflectivity to obtain cross sectional tomograms of the eye.

The Humphrey OCT employs the principle of low coherence interferometry based upon the Michelson interferometer. In a Michelson interferometer, the light from a source is split into a sample path and a reference path containing a mirror. Light reflected back from the sample path and the reference path will create an interference pattern on a detector if the optical path lengths between the reference and sample are identical. Adjusting the length of the reference path will allow a semi-transparent sample, such as the retina, to be cross-sectionally scanned.

The Super-Luminescent Diode (SLD) used in the Humphrey OCT Scanner permits a short coherence length in air. Accounting for the index of refraction of the eye, this translates to an even shorter coherence length within the retina. The SLD emits near infrared light which is scattered by the various interfaces and structures of the retinal tissue. As the reference arm is moved, a depth profile of the retina is produced which is similar to ultrasound A-scan. The profile plots variations in optical reflectivity between the different layers of the retina. Two mirrors mounted to galvanometers deflect the SLD beam within the eye. Scanning the retina in this manner produces cross-sectional images similar to ultrasound B-scan but of much higher resolution. The tomographic images of the retina produced by the OCT scanner provide an important tool in the diagnosis of retinal disorders and diseases that manifest themselves in the posterior pole of the eye.

5. This device will be used in the same manner as all OCT scanner devices are used for two dimensional cross-sectional imaging of the posterior segment of the eye. It incorporates the original intended uses of our earlier claimed substantially equivalent products. It is used primarily for diagnosing and monitoring retinal diseases and disorders that manifest themselves in the posterior pole of the eye. Clinical studies with the OCT have demonstrated its effectiveness in detecting and quantifying the extent of macular edema, macular holes, retinal detachments and central serious chorioretinopathy.

6. The modified OCT is substantially equivalent to the predicate device. One of the differences between the two devices are that the new OCT combines many of the separate components which were utilized into one more cohesive unit. The two devices are very similar in materials and energy source. The primary differences between the two are the way the exteriors are designed and their appearance. The new OCT has a redesigned delivery system. This improvement permits a greater field of view, a longer working distance, the introduction of the Landmark system and a new internal fixation system.

Clinical studies were mentioned above.